NOV 21 2008

K082553

RexaDerm, Inc.

3156 Doolittle Drive ♦ Northbrook, Illinois 60062♦ 847-562-0146

August 19, 2008

510(k) SUMMARY

1. Submission Owner and Correspondent:
   a. RexaDerm, Inc.
   b. Address:
      3156 Doolittle Drive
      Northbrook, Illinois 60062
   c. Phone: 847-562-0146
   d. Fax: 847-562-0146
   e. Contact Person:
      Clyde R. Goodheart, MD, President

2. Name of Device: RexaStom™ Oral Ease
   Trade name: RexaStom Oral Ease
   Common or usual name: Dressing, Wound and Burn, Hydrogel w/Drug or Biologic
   Classification names: Dressing, Wound and Burn, Hydrogel w/Drug or Biologic

3. Devices to Which New Device is Substantially Equivalent:

Gelclair Concentrated Oral Gel, Sinclair Pharmaceuticals	K013056
Aloclair Oral Rinse, Sinclair Pharmaceuticals	K023155

4. Device Description:

RexaStom Oral Ease is a dry, wafer or matrix type material, similar to coarse blotting paper. For mucositis, it is supplied in a 2.5-cm circular format, packaged in a vacuum-sealed, foil packet. Its ingredients are either food-grade or generally regarded as safe and therefore the wafer material is safe when swallowed. RexaStom is designed to be physiologically compatible with both intact and compromised tissue in the mouth, and provides temporary management of pain associated with various types of injuries to the mouth.

RexaStom's primary mode of action for pain relief is that it adheres to the wound surface, conforms to the contour of the wound, and protects the wound from contamination and irritation by forming a temporary protective barrier that is similar to the natural mucosa.

5. Intended Use of the Device

The indications for RexaStom are the same as for the predicate devices:

RexaStom™ Oral Ease has a mechanical barrier action indicated for the temporary relief of pain by adhering to the mucosal surface of the mouth, covering and soothing oral lesions of various etiologies. The lesions include oral mucositis resulting from chemo- or radiation therapy, stomatitis, irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, aphthous ulcers, or other diseases or conditions of the oral mucous surfaces.

6. Technological Characteristics of the Device Compared to Predicate Devices:

RexaStom, like the predicate devices cited in this 510(k), adheres to the wound surface, conforms to the contours of the wound, and provides temporary management of pain by forming a protective barrier over the wound, similar to undamaged natural mucosa. All these barriers manage pain by protecting the wound from contamination and irritation. They all slowly dissolve in the mouth, and all are safe if swallowed. Thus, the indication for use and the mode of action of this device are identical to those of predicate devices. We have found that the coating behavior of RexaStom in the mouth is the same as that for Gelclair, one of the predicate devices.

RexaStom is equivalent in composition to that of the cited predicate devices, except that because it is freeze-dried, glycerin is added to decrease brittleness, and preservatives have been omitted from its formulation. Further, because it is freeze-dried, it is light and easy to handle, and easier to use in public settings, because no mixing is needed. Because of this feature, we believe patients will be more likely to use the product for temporary relief of pain to make it easier for them to eat.

RexaStom contains five ingredients, all of which are food grade or approved by FDA for internal use, and generally regarded as safe. These ingredients are also in Gelclair, perhaps the closest predicate device. As it is now formulated, RexaStom omits flavoring, and is tasteless. Testing with more subjects may require addition of flavoring and possibly sweetener, which we assume will not require further approval.

Conclusion: RexaStom Oral Ease is substantially equivalent to the predicate devices in its indications and composition, and in its safety and effectiveness. Because the formulation of RexaStom is similar to, but more simple than, the predicate devices, the criteria for substantial equivalence have been met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Clyde R. Goodheart, M.D.
President
RexaDerm, Incorporated
3156 Doolittle Drive
Northbrook, Illinois 60062

Re: K082553
Trade/Device Name: RexaStom™ oral Ease
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: August 29, 2008
Received: September 3, 2008

Dear Dr. Goodheart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

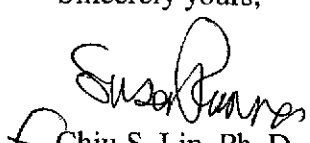
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082553

Indications for Use

510(k) Number (if known): Not known.

Device Name: RexaStom[tm] Oral Ease

Indications For Use:

RexaStom[tm] Oral Ease has a mechanical barrier action indicated for the temporary relief of pain by adhering to the mucosal surface of the mouth, covering and soothing oral lesions of various etiologies. The lesions include oral mucositis resulting from chemo- or radiation therapy, stomatitis, irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, aphthous ulcers, or other diseases or conditions of the oral mucous surfaces.

Note that the indications for RexaStom are the same as for the predicate devices.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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